



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,356	07/23/2001	Ioannis Pallikaris	10781/9	3390

7590 08/27/2003

VINCENT J. GNOFFO
BRINKS, HOFER, GILSON & LIONE
455 N. CITYFRONT
NBC TOWER, SUITE 3600
CHICAGO, IL 60611

EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/27/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,356

Applicant(s)

PALLIKARIS ET AL.

Examiner

Victor X Nguyen

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 24 and 25 is/are rejected.
- 7) ☒ Claim(s) 16-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 14-15 and 24-25 are rejected under 35 U.S.C. 102 (e) as being anticipated by Amano (U.S. 6,506,198).

Regarding claims 1 and 3, Amano shows in figures 1, 2, a mechanical device (1) includes a separator (21a), wherein the device can preserve the separated epithelial layer without rupturing the disk and without substantial epithelial cell loss; The intended use “wherein the device is suitable for separating the epithelial layer from the cornea stroma” is not given patentable weight because only the structure of the separator device is being claimed; and wherein the separator (21a) is not sharp enough to excise corneal tissue.

Regarding claims 2, 4, 14-15 and 24-25, Amano shows in figures 1, 2, wherein a ring (31) seats on the eye, wherein a separator support (21a) fits in the groove (fig. 3, items 22a, 23a) and an oscillation device (12) provides motion and vibration to the separator (21a); wherein the separator (21a) is not sharp enough to excise corneal tissue.

Regarding claims 5 and 6, Amano shows in figures 1, 2 and col. 7 lines 4-21, wherein a travel of the separator (21a) is controlled to produce an epithelial disk hinged to the border of the separation.

Art Unit: 3731

Regarding claims 7 and 8, Amano shows in figures 1, 2, wherein the ring (31) includes a circumferential groove (fig. 3 items 22a, 23a) on the side of the eye and suction (3) is applied to the circumferential groove to ensure stable mounting of the ring (31).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-12 are rejected under 35 U.S.C 103 (a) as being unpatentable over Amano (6,506,198) in view of Bair et al (6,126,668) .

Regarding claim 9, Amano discloses the invention substantially as claimed. However, Amano does not disclose the separator oscillates with frequency ranging from about 10 Hz to about 10,000 Hz . Bair et al teaches the separator oscillates with frequency ranging from about 8,000-15,000 rpms, which is about 133 Hz-250 Hz (col. 13 lines 8-14). It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Amano by adding the separator oscillating with a frequency ranging from about 8,000-15,000 rpms, which is about 133 Hz-250 Hz as taught by Bair et al in order to produce an optimal rate of oscillation for the cutting instrument.

Claims 10-12 are rejected under 35 U.S.C 103 (a) as being unpatentable over Amano (6,506,198) in view of Bair et al (6,126,668) and further in view of Tanne (4,665,914).

Regarding claims 10-12, Amano in view of Bair et al disclose a device having all limitations substantially as claimed. However, the combination fails to disclose the separator

Art Unit: 3731

oscillation provided by electromagnetic forces or piezoelectric forces on the separator. Tanne (see col. 5 lines35-68) teaches the separator oscillation provided by electromagnetic forces or piezoelectric forces on the separator.

It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify the combination of Amano in view of Bair et al by adding the separator oscillation provided by electromagnetic forces or piezoelectric forces on the separator because this would have been merely an alternate and analogous way to produce the oscillation in the modified Amano device.

Claim 13 is rejected under 35 U.S.C 103 (a) as being unpatentable over Amano (6,506,198) in view of Ruiz et al (5,133,726).

Regarding claim13, Amano discloses the invention substantially as claimed. However, Amano does not disclose the device includes rotating gears. Ruiz et al teaches a corneal shaping device that oscillates by the use of rotating gears (figures 1, 10). It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Amano by adding the oscillation by rotating gears as taught by Ruiz because this would have been merely an alternate and analogous way to produce the oscillation in the modified Amano device.

Allowable Subject Matter

3. Claims 16-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3731

4. The following is a statement of reasons for the indication of allowable subject matter:

None of the prior art of record disclose or suggest wherein a rotating drum and where the separated epithelial disk is rolled on the drum.

Response to Arguments

Applicant's arguments filed 06/02/2003 have been fully considered but they are not persuasive.

As the examiner has pointed out above, the device of Amano shows in figures 1, 2, a mechanical device (1) includes a separator (21a), wherein the device can preserve the separated epithelial layer without rupturing the disk and without substantial epithelial cell loss. Furthermore, it is noted that a recitation of the intended use (wherein the device is suitable for separating the epithelial layer from the cornea stroma) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In addition, the device of Amano inherently is capable of performing the same function as the applicant's device to separate the epithelial layer from the corneal. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, the claimed invention is not patentable over Amano device.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 3731

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen
Examiner
Art Unit 3731

Vn *vd*
August 23, 2003

Julian W. Woo
Julian W. Woo
Primary Examiner